



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,167	10/06/2003	Francine Goulet	238813US-6 DIV	5723
22850	7590	05/17/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			LANDREM, KAMRIN R	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,167

Applicant(s)

GOULET ET AL.

Examiner

Kamrin R. Landrem

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/6/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 31 is objected to because of the following informalities: Claim 31 depends from cancelled claim 24. For examination purposes the Examiner has assumed that claim 31 should depend from claim 25. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-31,33-38,43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 5,613,982) in view of Campbell et al (USPN 5,067,962) and Uematsu et al (USPN 6,146,882).

Goldstein discloses the method for preparing a connective tissue bioprosthesis (3:14-24) for animals or humans (2:45-53). The tissue is decellularized then incubated in a nutrient solution containing extracellular matrix protein such as fibronectin and glycosaminoglycan for a period effective for the binding of the substances to the tissue matrix (8:55+). The tissue is chemically treated and then the matrix is colonized by heterologous or autologous fibroblast cells (9:1-2 and 9:34-67). The matrix also includes growth factors (9:55+). Goldstein discloses the method as claimed however Goldstein fails to specifically recite the type of incubator used as well as the specific shape of the bioprosthesis. Uematsu et al teaches an incubator 10 with

Art Unit: 3738

vibrating plate 25 that can efficiently incubate and cool multiple samples (3:5-10). With reference to Figure 3 Campbell teaches a bioprosthetic ligament that comprises a natural ligament 11 to two bone plug attachments 23,24 located at the natural attachment site thus overcoming existing problems of ligament prostheses and providing an improved replacement for the anterior cruciate ligament (1:60-2:44). Therefore in view of the teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method disclosed by Goldstein to incorporate the incubator as taught by Uematsu to prepare tissue for multiple prostheses at once in addition to using the specific shape as taught by Campbell to produce an improved connective tissue substitution.

Claims 32 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein in view of Campbell and Uematsu as applied to claims 25-31,33-38, 43 and 44 above, and further in view of Altman (USPN 6,287,340).

Goldstein as modified by Campbell and Uematsu as discussed above, discloses the method as claimed. Goldstein as modified by Campbell and Uematsu discloses all of the claimed elements except for the particulars pertaining to the type of collagen matrix. Altman et al teaches the method of producing a bioengineered cruciate ligament with a matrix material composed of collagen gel (2:29-30) and a coating to which cells can adhere in a wide range of ligament types and adapting the anchor size to reflect the size of the specific ligament to be produced (2:50-65). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method disclosed by Goldstein to incorporate collagen gel to promote cell adhesion and produce a prosthesis that is customized in function and size for each particular application.

Conclusion

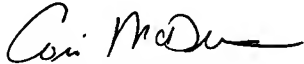
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

krl


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700